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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,027	03/02/2004	John A. Giordano	48508-00014	9737

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EXAMINER

CHOI, FRANK I

ART UNIT PAPER NUMBER

1616

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,027

Applicant(s)

GIORDANO ET AL.

Examiner

Frank I. Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 187-201 and 217-231 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 187-201 and 217-231 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The finality of the prior Office Action (9/16/2005) is withdrawn in light of the new grounds of rejection herein.

Information Disclosure Statement

The information disclosure statement filed 4/10/2006 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The list of claims does not meet the above requirements. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

((e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 187-190, 193, 195, 196, 198 are rejected under 35 U.S.C. 102(e) as being anticipated by Bydlon et al. (US 2003/0050341).

Bydlon et al.. expressly discloses a composition containing Vitamin A (beta-carotene), Vitamin D3 (cholecalciferol), Vitamin C (ascorbic acid), Vitamin E, folic acid, Vitamin B1, Vitamin B2 (riboflavin), Vitamin B6 (pyridoxine), Vitamin B12 (cyanocobalamin), niacin (niacinamide), calcium, iron (ferrous fumarate), magnesium, zinc, and copper as a dietary supplement (paragraph 0042, Claim 61).

The Rule 131 declaration (2/11/2005) filed to overcome a different art reference is not sufficient to overcome the rejection herein as the declaration only indicates a prior date of May 2, 2002. The prior art reference above has an effective filing date of September 12, 2001 via a provisional application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 187-201, 217-231 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bydlon et al. (US 2003/0050341) in view of Moshedy (US Pat. 5,770,215) and one of The Merck Index or Briggs et al. (US Pat. 4,752,479).

Bydlon et al.. discloses a composition containing Vitamin A (beta-carotene), Vitamin D3 (cholecalciferol), Vitamin C (ascorbic acid), Vitamin E, folic acid, Vitamin B1, Vitamin B2 (riboflavin), Vitamin B6 (pyridoxine), Vitamin B12 (cyanocobalamin), niacin (niacinamide), calcium, iron (ferrous fumarate), magnesium, zinc, and copper as a dietary supplement and amount ranges of the same (see entire document, especially paragraph 0042, Claim 61). It is

Art Unit: 1616

disclosed that pyridoxine can be in the form of pyridoxine HCl, calcium in the form of calcium carbonate, zinc in the form of zinc oxide, iron in the form of chelate or salt, copper in the form of cupric oxide and that magnesium can be present in any biologically acceptable form (paragraph 0028, paragraphs 0036-0041).

Moshyedi discloses that a dietary supplement that contains at least one mineral or vitamin and that all combinations of minerals and vitamins are within the scope of the invention (Column 4, lines 29-34). It is disclosed that the vitamins in compositions normally range from about 5% to about 1000% of the RDA and that the vitamins include, vitamin A or beta carotene, vitamin D or cholecalciferol, vitamin E, vitamin C or ascorbic acid, nitrate salts of thiamin, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamine and that the minerals can preferably range from at least 5% of RDA and include oxide, carbonate or fumarate salts of calcium, magnesium, iron and zinc (Column 5, lines 58-67, Columns 6-8).

The Merck Index discloses that magnesium oxide can be used therapeutically, that thiamine can be in the form of thiamine mononitrate and that Vitamin E can be in the form of d,l-alpha-tocopherol acetate (Pages 892,893,1464,1579,180).

Briggs et al. discloses a dietary supplement which can include calcium carbonate, magnesium oxide, ferrous fumarate, cupric oxide, zinc oxide, vitamin A, vitamin D or cholecalciferol, vitamin B1 or thiamin mononitrite, vitamin B2 or riboflavin, vitamin B6 or pyridoxine hydrochloride, vitamin B12 or cyanocobalamin, vitamin C or ascorbic acid, vitamin E or dl-alpha tocopheryl acetate, folic acid and niacinamide (Column 2, lines 48-68, Column 3, Column 4, lines 1-10, 45-60).

Art Unit: 1616

The prior art discloses a composition containing the claimed vitamins and minerals and no other added minerals or vitamins. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of calcium carbonate, magnesium oxide, zinc oxide, copper oxide, thiamine mononitrate and d,l-alpha-tocopherol acetate in the claimed vitamin and mineral combination, or the amount ranges. However, the prior art amply suggests the same as the prior art discloses that calcium can be in the form of calcium carbonate, that magnesium, zinc and copper can be in the form of their oxides, that thiamine can be in the form of thiamine mononitrate and that vitamin E can be in the form of d,l-alpha-tocopheryl acetate. Further, the prior art disclose amounts and ranges of amounts which encompass or overlap the claimed amounts. As such, one of ordinary skill in the art would have been motivated to use calcium carbonate, magnesium oxide, zinc oxide, copper oxide, thiamine mononitrate and d,l-alpha-tocopherol acetate with the expectation that the same would be suitable sources of calcium, magnesium, zinc, copper, thiamine and vitamin E. Also, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of "about 1-5%" while the claim was limited to "more than 5%." The court held that "about 1-5%" allowed for concentrations slightly above 5% thus the ranges overlapped.).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 187-201 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 187-207 of copending Application No.

11/296,210. Although the conflicting claims are not identical, they are not patentably distinct from each other because although the conflicting claims are not identical, they are not patentably distinct from each other because they both set forth compositions containing the same vitamins and minerals with claims of the ‘210 application anticipating the claims of the present by claiming the same forms of said vitamins and minerals. The ‘210 application claims amounts of calcium ranging from about 90 mg to about 110 mg (claim 200), iron ranging 59-71 mg in integers (claim 202), and copper in the amounts of 1.8, 1.9, 2.0, 2.1 and 2.2 mg (claim 207).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 187-201, 217-231 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 187-207 of copending Application No. 11/296,210 in view of in view of Bydlon et al. (US 2003/0050341)

The '210 application and Bydlon et al. are cited for the same reasons as above and are incorporated herein to avoid repetition.

The claims of the '210 application disclose the claimed invention as indicated above. The difference between the claims of the '210 application and the claimed invention is that said claims, other than for calcium and iron and copper do not expressly disclose amounts the range amounts of the vitamins and other minerals. However, the prior art amply suggests the same as the prior art ranges encompass the claimed amounts. As indicated above, where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

Therefore, the claimed invention, as a whole, would have been obvious modification of the claims of the '210 application to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of said claims and the cited prior art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday,

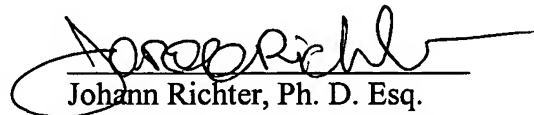
Art Unit: 1616

8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 16, 2006


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